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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,590	09/09/1999	ELIZABETH MOYER	00211-US-NEW	2967

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ELAN PHARMACEUTICALS, INC.
INTELLECTUAL PROPERTY DEPARTMENT
800 GATEWAY BOULEVARD
SOUTH SAN FRANCISCO, CA 94080

EXAMINER

DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

19

DATE MAILED: 02/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/393,590

Applicant(s)

Moyer et al.

Examiner

S. Devi, Ph.D.

Art Unit

1645

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Dec 5, 2002
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 ~~is/are~~ pending in the application.
- 4a) Of the above, claim(s) 29-53 ~~is/are~~ withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5, 8, 14-17, 21, and 27 ~~is/are~~ rejected.
- 7) ☒ Claim(s) 4, 6, 7, 9-13, 18-20, 22-26, and 28 ~~is/are~~ objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 16. 6) ☐ Other:

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Reply

- 1) Acknowledgment is made of Applicants' reply filed 12/05/02 (paper no. 18) in response to the non-final Office Action mailed 06/05/02 (paper no. 15).

Status of Claims

- 2) No claims have been amended.
Claims 1-58 are pending.
Claims 1-28 are under examination.

Information Disclosure Statement

- 3) Acknowledgment is made of Applicants' information disclosure statement filed on 06/10/2002 (paper no. 16). The information referred to therein has been considered and a signed copy of the same is attached to this Office Action (paper no. 19).

Prior Citation of Title 35 Sections

- 4) The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior Office Action.

Prior Citation of References

- 5) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Rejection(s) Maintained

- 6) The rejection of claims 1-3, 5, 8, 14-17, 21 and 27 made in paragraph 10 of the Office Action mailed 06/05/02 (paper no. 15) under 35 U.S.C § 102(b) as being anticipated by Schantz *et al.* (*J. AOAC* 61: 96-99, 1978 - Applicants' IDS), is maintained for reasons set forth therein and herebelow.

Applicants cite case law and contend that Schantz *et al.* do not teach a stable liquid pharmaceutical botulinum toxin formulation as claimed in claim 1 or 16. Applicants submit that Schantz *et al.* only teach formulations A and B, both having a pH outside of the range of between about pH 5.0 and pH 6.0. Applicants point to parts of Schantz's disclosure on pages 96 and 97

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and contend that both of the Schantz formulations have stability problems, i.e., loss of toxicity 'if frozen' (pH 4.2) or loss of toxicity at room temperature 6.2. Applicants acknowledge that Schantz *et al.* teach formulation A with pH 4.2 at room temperature, preferably 18-24°C. Applicants state that a formulation with pH 4.2 at room temperature preferably 18-24°C does not anticipate a pH range of about 5 to pH 6.0 at 0-10°C. Applicants discuss the Schantz formulation B having a pH of 6.2, although it was never included in the art rejection of record. Applicants then allege that the Office Action is incorrect in asserting that a pH of 4.2 is about 5.0.

Applicants' arguments have been carefully considered, but are non-persuasive. It should be noted that the instant claims do not include any limitations about the freezing ability or capacity of the claimed composition. Instead, the claimed formulation is required to be in a 'stable' form. Furthermore, the instant specification does not contain a precise description of what pH must be included or excluded from the recitation "about" pH 5.0. Therefore, Schantz's pH of 4.2 is viewed as being encompassed in the scope of the limitation in the instant claims: i.e., the lower range of "about pH 5.0". As set forth in paragraph 10 of the Office Action mailed 06/05/02 (paper no. 15), although Schantz's preferable room temperature is 18-24 degrees centigrade, non-preferable room temperatures do not exclude, for example, 10 degree centigrade, which based on the locality, is room temperature. The rejection stands.

Prior Art

7) The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

- Ho *et al.* (US 5,780,431) disclosed a method of producing a stable liquid pharmaceutical formulation by having the active biological component in acetate, phosphate, carbonate, succinate, citrate, borate, formate and lactate buffers with a pH ranging between about 2.0 to about 5.0, or between pH 6.0 to about pH 9.0 (see entire patent, especially claims).

Remarks

8) Claims 1-3, 5, 8, 14-17, 21 and 27 stand rejected. Claims 4, 6, 7, 9-13, 18-20, 22-26 and 28 are objected to for being dependent on a rejected claim.

9) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is able to receive transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.

11) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD
S. DEVI, PH.D.
PRIMARY EXAMINER

February, 2003